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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/513,888 | 02/25/00 | CROCE | C 9855-30U1 |

000570 HM22/1023
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| EXAMINER | |
|---|---|
| LOEB, B | |
| ART UNIT | PAPER NUMBER |
| 1636 | 7 |

DATE MAILED: 10/23/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/513,888 | CROCE ET AL. | |
| | Examiner | Art Unit | |
| | Bronwen M. Loeb | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-25, 27, 30, 34-36, 41-43, 45, 47-58, 63-68, 73-75, 84, 86, 87, and 90-97* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Continuation of Disposition of Claims: Claims pending in the application are 1-25, 27, 30, 34-36, 41-43, 45, 47-58, 63-68, 73-75, 84, 86, 87, and 90-97.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, 67, 90, 91, and 94-97, drawn to an isolated polynucleotide having a portion which anneals to a human *FEZ1* gene, a kit which may use such a polynucleotide and an animal cell transformed with such a polynucleotide, classified in class 536, subclass 23.1 and class 435, subclasses 7.23 and 91.1.

II. Claim 27, drawn to a genetically altered animal into which at least the *FEZ1* coding region is introduced, classified in class 800, subclass 13.

III. Claim 30, drawn to an isolated Fez1 protein, classified in class 530, subclass 350.

IV. Claims 34, 35 and 67, drawn to an isolated antibody against human Fez1 protein, a hybridoma producing such antibodies and a method which may use such an antibody, classified in class 530, subclass 387.1 and class 435, subclasses 7.23 and 326.

V. Claims 36, 41-43 and 45, drawn to a method of determining the cancerous status of a sample tissue by examining *FEZ1* expression, nucleotide sequence of a *FEZ1*-associated polynucleotide, length of a *FEZ1*-trascript-associated polynucleotide or splicing of a *FEZ1* transcript, classified in class 435, subclasses 4 and 6.

VI. Claims 47-49, drawn to methods of modulating abnormal proliferation of a human cell by providing an exogenous source of Fez1 protein, classified in class 434, subclass 375.

VII. Claims 50-56, drawn to methods of modulating abnormal proliferation of a human cell by providing an expression vector which encodes a functional Fez1 protein, classified in class 514, subclass 44 and class 435, subclass 375.

VIII. Claim 57, drawn to a method of inhibiting tumorigenesis in a human cell using an expression vector encoding a functional Fez1 protein, classified in class 514, subclass 44, and class 435, subclass 375.

IX. Claim 58, drawn to a method of reversibly inducing proliferation of a cell by providing an inhibitor of *FEZ1* expression, classified in class 435, subclass 375.

X. Claim 63, drawn to a method of determining whether a test compound is an inducer of cell proliferation involving assessing *FEZ1* gene expression, classified in class 435, subclass 4.

XI. Claim 64, drawn to a method of determining whether a test compound is effective to retard abnormal proliferation of a cell having an altered *FEZ1* gene involving assessing *FEZ1* gene expression, classified in class 435, subclass 4.

XII. Claim 65, drawn to a method of determining whether Fez1 protein binds with polynucleotides having a test nucleotide sequence, classified in class 435, subclasses 6 and 7.1.

XIII. Claim 66, drawn to a method of identifying an inducer of cell proliferation involving assessing formation of a Fez1-polynucleotide complex, classified in class 435, subclass 7.1.

XIV. Claim 68, drawn to a method of inducing a cell to proliferate by inhibiting *FEZ1* expression, classified in class 435, subclass 375.

XV. Claim 73, drawn to an enhanced human cell culture technique involving inhibition of *FEZ1* expression, classified in class 435, subclass 366.

XVI. Claim 74, drawn to a method of detecting *FEZ1* expression in a sample tissue involving a labeled antibody against Fez1, classified in class 435, subclass 7.1.

XVII. Claim 75, drawn to a method of determining whether a test compound is useful for alleviating a disorder associated with aberrant tubulin polymerization involving tubulin and Fez1, classified in class 435, subclass 7.1.

XVIII. Claims 84 and 86, drawn to a method of determining whether a test compound is useful for alleviating a disorder associated with aberrant phosphorylation of Fez1 involving assessing the extent of phosphorylation of Fez1, classified in class 435, subclass 7.1.

XIX. Claim 87, drawn to a method of determining whether a test compound is useful for alleviating a disorder associated with aberrant binding of Fez1 with a protein with which Fez1 normally binds by assessing binding between Fez1 and the protein, classified in class 435, subclass 7.1.

XX. Claim 92, drawn to a method determining whether a test compound is an inhibitor of cell proliferation by assessing expression of *FEZ1,* classified in class 435, subclasses 4 and 375.

XXI. Claim 93, drawn to a method of inhibiting tumorigenesis in a human by affecting gene expression of *FEZ1*, phosphorylation state of Fez1 or specific binding reaction involving Fez1, classified in class 435, subclass 375.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-IV are distinct products from each other, having different chemical, biological, structural and functional distinctness from each other, and are not disclosed for use together.

Groups V-XXI are distinct methods from each other, having different starting material, different outcomes and different uses.

Inventions I and V, VII, VIII, X, XI, and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the

polynucleotide product can be used in a variety of materially different processes as evidenced by the several methods claimed which may use a polynucleotide.

Inventions III and VI, XII, XIII, and XVII-XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein product can be used in a variety of materially different processes as evidenced by the several methods claimed which may use a protein.

Inventions IV and V, X, XI, XVI, and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody product may be used in a variety of materially different processes as evidenced by the several methods claimed which may use antibody.

Inventions I and VI, IX, XII-XIX, and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotide product of Invention I is not disclosed as capable of use with any of the processes of Inventions VI, IX, XII-XIX, and XXI.

Inventions II and V-XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not discloses as capable of use together.

Inventions III and V, VII-XI, XIV-XVI, XX and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the protein product of Invention III is not disclosed as capable of use with any of the processes in Inventions V, VII-XI, XIV-XVI, XX and XXI.

Inventions IV and VI-IX, XII-XV, XVII-XIX and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibody of Invention IV is not disclosed as capable of use in any of the processes of Inventions VI-IX, XII-XV, XVII-XIX and XXI.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is 703-605-1197. The examiner can normally be reached on Monday through Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliot can be reached on 703-308-4003. The fax phone number for the organization where this application or proceeding is assigned is 703-305-4242 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bronwen M. Loeb
October 10, 2000

ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER